

**K150888 Shape-HF Cardiopulmonary Testing System**Jan 21, 2016  
294 days to decisionK150888 · Product code: **BTY** · Anesthesiology  
Source: <https://www.510kdatabase.net/k150888/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Predicted Values, Pulmonary Function (BTY)
Date received	Apr 2, 2015
Decision date	Jan 21, 2016
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shape Medical Systems, Inc.</b>
Location	Minneapolis, MN, US
Contact	BERNARD HORWATH
510(k) history	2 submissions · 2 cleared · 2009-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150888/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 24, 2026